

## SUBLICENSE AND TECHNOLOGY TRANSFER AGREEMENT

This sublicense and technology transfer agreement (this **Sublicense Agreement**) is made and entered into on July 15, 2014 (the "**Effective Date**") and is amended and restated as of March <sup>23</sup>, 2017 by and between:


- (1) **Bristol-Myers Squibb Company**, a Delaware corporation, with offices at 345 Park Avenue, New York, New York, U.S.A. (BMS);
- (2) **The Medicines Patent Pool Foundation**, a non-profit foundation registered under the laws of Switzerland, and having a principal place of business at Rue de Varembe 7, Geneva 1202, Switzerland (MPP); and
- (3) **Aurobindo Pharma Ltd.**, a company organized under the laws of India, with its registered office at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad, 500 038 T.S. India (the **Sublicensee**).

Each of BMS, MPP and the Sublicensee is referred to in this Sublicense Agreement as a **Party**. BMS, MPP and the Sublicensee are collectively referred to in this Sublicense Agreement as the **Parties**.

### Preliminary Statements

The Parties recognize that the HIV/AIDS pandemic constitutes a serious health crisis and are entering into this Sublicense Agreement as part of a humanitarian endeavor with the aim of increasing effective access to, and the use of the Licensed Compound (as defined below), an antiretroviral used in combination therapy for the treatment of HIV infection, in the Territory (as defined below). In keeping with the purpose of this Sublicense Agreement, the Sublicensee understands and acknowledges that the Licensed Compound and Licensed Products (both as defined below) are to be made only for use in, and for the benefit of patients in, the Territory on the terms set out in this Sublicense Agreement. In addition, it is the spirit and purpose of this Sublicense Agreement to enable low-cost, affordable therapies in the face of the HIV/AIDS pandemic, and it is expected that the Sublicensee will make every effort to ensure low-cost and affordable access to the Licensed Compound and Licensed Products in the Territory.

### Whereas

- (A) MPP is a non-profit organization with a mission to improve the health of people living in the developing world by increasing access to quality, safe, efficacious and affordable HIV medicines by facilitating access to intellectual property on these medicines.
  - (B) BMS Controls (as defined below) the Licensed Patents Rights and Licensed Manufacturing Know-How (both as defined below) with respect to the Licensed Compound and the Licensed Products with respect to the Territory.
  - (C) On 11 December 2013, BMS and MPP have entered into a license and technology transfer agreement (the **License Agreement**) whereby BMS has granted to MPP a license on the Licensed Patent Rights and Licensed Manufacturing Know-How, solely to allow MPP to grant sublicenses to various manufacturers of pharmaceuticals products that would be interested in obtaining such a sublicense, in order to promote access to the Licensed Products in the Territory.
  - (D) The Sublicensee desires to obtain a sublicense from MPP on these patent and know-how rights as set out in this Sublicense Agreement and MPP desires to grant such sublicense to the Sublicensee, in order to promote access to the Licensed Products in the Territory;
  - (E) The Parties desire to provide for certain technology transfer arrangements to assist with the transfer to Sublicensees (as defined below) of the Licensed Manufacturing Know-How (as defined below) related to the Licensed Compound and the Licensed Products.
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Now, therefore, in consideration of the foregoing and the mutual agreements set out in this Sublicense Agreement, the Parties agree as follows.

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1. **DEFINITIONS AND INTERPRETATION**

1.1 **Definitions**

For the purposes of this Sublicense Agreement, the following definitions shall apply:

**Affiliate** of a Person means any Person which, directly or indirectly, is controlled by, controls or is under common control with such Person. For the purposes of this definition, the term **control** as used with respect to a Person shall mean the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise.

**BMS Sole Inventions** has the meaning given in clause 9.1(a).

**Business Day** means a day other than Saturday, Sunday or any day on which commercial banks located in New York, New York, U.S.A. are authorized or obligated by law to close.

**Combination Product** means a formulated and finished pharmaceutical product containing the Licensed Compound or the Licensed Products in combination with any other active pharmaceutical ingredient, including any co-formulation, co-packaged product, bundled product or other type of combination product.

**Commercialization** or **Commercialize** means activities directed at obtaining pricing and reimbursement approvals, marketing, promoting, distributing, importing or selling a Licensed Product.

**Confidential Information** means all trade secrets, processes, formulae, data, know-how, improvements, inventions, chemical or biological materials, techniques, marketing plans, strategies, customer lists, or other information that has been created, discovered, or developed by a Party or any of its Affiliates, or has otherwise become known to a Party or any of its Affiliates, as well as any other information and materials that are deemed confidential or proprietary to or by a Party or any of its Affiliates (including all information and materials of a Party's (or its Affiliates') customers and any other Third Party and their consultants), regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated to the other by the disclosing Party in oral, written, graphic or electronic form. Confidential Information will include the Licensed Manufacturing Know-How.

**Controlled** or **Controls**, when used in relation to intellectual property, will mean the legal authority or right of a Party (or any of its Affiliates) to grant a license or sublicense of intellectual property rights to another Party, or to otherwise disclose proprietary or trade secret information to such other Party, without breaching the terms of any agreement with a Third Party, infringing upon the intellectual property rights of a Third Party, or misappropriating the proprietary or trade secret information of a Third Party.

**Development** and **Develop** means non-clinical and clinical drug development activities reasonably related to the development and submission of information to a Regulatory Authority, including toxicology, pharmacology and other discovery efforts, test method development and stability testing, process development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical studies (including pre- and post-approval studies and specifically excluding regulatory activities directed to obtaining pricing and reimbursement approvals).



**Field** means the prevention, treatment or control of HIV and AIDS.

**HIV/AIDS** means the human immunodeficiency virus and acquired immunodeficiency syndrome.

**Licensed Compound** means the compound listed in Schedule A.

**Licensed Manufacturing Know-How** means all technical information and know-how known to or Controlled by BMS or its Affiliates as of the Effective Date (including all manufacturing data, the percentages and specifications of ingredients, the manufacturing process, specifications, assays, quality control and testing procedures) that is identified by BMS as primarily and directly relating to, and reasonably necessary for, the making of the Licensed Products in the same manner that such Licensed Products have been made by BMS prior to the Effective Date.

**Licensed Patent Rights** means:

- (a) the patents and patent applications of BMS in the Territory related to the Licensed Compound, including those listed on Schedule B;
- (b) any continuation, continuation-in-part (but only to the extent that such application includes new data in support of claims previously submitted in a prior originally filed application), divisional, and continued-prosecution applications of any patent applications included in paragraph (a);
- (c) any patents issuing from any patent applications included in the paragraphs (a) and (b),

in each case, including any renewals, extensions, patents of addition, supplementary protection certificates, revivals, re-examinations, and reissues thereof.

**Licensed Products** means any human pharmaceutical products produced under license from MPP in the Field and containing the Licensed Compound as one of its active ingredients (or as its sole active ingredient), in finished form or in such other forms, presentations, doses and formulations.

**Net Sales** means with respect to a given calendar quarter, the total amount invoiced by the Sublicensee for sales of the Licensed Products in the countries within the Territory where Licensed Patents Rights are in force, less freight, insurance, packing, shipping and custom duty, VAT, excise tax, sales tax, and packing for shipment, to the extent consistent with generally accepted accounting principles as consistently applied across all products of the Sublicensee and in line with the deductions reasonably expected in the relevant market.

**Non-Territory Patent Rights** means:

- (a) the patents and patent applications of BMS outside of the Territory related to the Licensed Compound, including those listed on Schedule B;
- (b) any continuation, continuation-in-part (but only to the extent that such application includes new data in support of claims previously submitted in a prior originally filed application), divisional, and continued-prosecution applications of any patent applications included in paragraph (a);
- (c) any patents issuing from any patent applications included in the paragraphs (a) and (b),

in each case, including any renewals, extensions, patents of addition, supplementary protection certificates, revivals, re-examinations, and reissues thereof.



**Person** means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, governmental authority, association or other entity or other form of business organization.

**Product Trademark** means the trademark set out in Schedule E.

**Regulatory Authority** means any national or supranational governmental authority that has responsibility in the Territory over the Development and/or Commercialization of the Licensed Compound and Licensed Products.

**Sanctions** shall have the meaning given in the definition of "Sanctions Target".

**Sanctions Authorities** shall have the meaning given in the definition of "Sanctions Target".

**Sanctions Target** shall mean an individual or entity that is, or is owned or controlled by one or more individuals or entities that are: (i) the target of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control (OFAC), the U.S. Department of State, the European Union or its Member States or another sanctions authority with jurisdiction over any Party (together, the Sanctions Authorities) (collectively Sanctions); or (ii) located, organized or resident in a country or territory that is the target of country-wide or territory-wide Sanctions or (iii) listed on OFAC's Consolidated Sanctions List or any equivalent list of parties designated by the European Union.

**Sublicense Agreement** means this agreement, together with all attached Schedules, as the same may be amended or supplemented from time to time.

**Technical Transfer Package** has the meaning given to in clause 4.2.

**Territory** means the countries listed in Schedule D and such other or different countries as the Parties may agree in writing.

**Third Party** means any Person other than MPP, BMS, the Sublicensee and their respective Affiliates.

## 1.2 Interpretation

In this Sublicense Agreement:

- (a) clause headings are for convenience only and are not intended to affect the interpretation of this Sublicense Agreement;
- (b) where any word or phrase has a defined meaning, any other form of that word or phrase has a corresponding meaning;
- (c) words in the singular include the plural and vice versa;
- (d) any reference to "includes" or "including" are to be construed as indicative and non-exhaustive lists;
- (e) unless otherwise specified or prevented by applicable laws, reference to "writing" includes faxes, email, letters, digital signatures or certificates or any other legible form of writing;
- (f) if a period of time is specified and dates from a given day or the day of an act or event, it is to be calculated exclusive of that day; and



- (g) except to the extent expressly specified to the contrary, in the event of any inconsistency between any clause, any attachment or other document incorporated by reference, the clauses override the attachments, and the attachments override any other incorporated documents incorporated by reference, to the extent of any inconsistency.

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**2. LICENSE GRANT**

**2.1 Licensed Patent Rights and Licensed Manufacturing Know-How**

- (a) Upon the terms and subject to the conditions set out in this Sublicense Agreement, MPP hereby grants to the Sublicensee, and the Sublicensee hereby accepts, a non-exclusive, non-sublicenseable, royalty-bearing (under the conditions of clauses 2.3 and 3), non-transferable license under the Licensed Patent Rights and the Licensed Manufacturing Know-How to make, or have made, use, offer for sale, sell, have sold, export or import the Licensed Compound and Licensed Products anywhere in the world exclusively for ultimate use in the Field in the Territory.
- (b) The Sublicensee will not have any right to practice the license granted under this clause 2.1 or otherwise exploit the Licensed Patent Rights and Licensed Manufacturing Know-How for any other purpose.

**2.2 Term of license grant**

The license granted to the Sublicensee in clause 2.1 with respect to Licensed Patent Rights will expire upon the expiration of the last-to-expire of the Licensed Patent Rights that are granted and in force, unless where terminated earlier in accordance with clause 13. Following the expiration of such licenses in the Territory, the licenses granted in clause 2.1 with respect to Licensed Manufacturing Know-How will be fully paid-up and perpetual.

**2.3 Relationship with the License Agreement**

- (a) The Sublicensee acknowledges and agrees that this Sublicense Agreement is subject to and subordinate to the License Agreement.
- (b) The Sublicensee hereby confirms that it has reviewed the terms and conditions of the License Agreement and agree to not perform any acts or omissions that would place MPP in breach of the License Agreement.
- (c) Under this Sublicense Agreement, the Sublicensee is entitled to make, have made, offer for sale, sell, have sold, export or import the Licensed Compound, whether inside or outside of the Territory, solely for the manufacture of Licensed Products exclusively for use in the Field in the Territory.
- (d) Under this Sublicense Agreement, the Sublicensee is entitled to offer for sale, sell, have sold the Licensed Products to customers outside of the Territory solely to the extent that such Licensed Products will be exclusively used in the Field in the Territory.
- (e) In the event that BMS or MPP becomes aware of any act or omission of a Sublicensee which constitutes a breach of this Sublicense Agreement, MPP will:
- (i) if the breach is capable of correction and does not give rise to an immediate right of termination under this Sublicense Agreement, direct the Sublicensee in writing to cure the breach within 90 days of MPP's notice, with a copy of that writing to BMS; and

- (ii) if the breach remains uncured at the end of the specified period, or if there are otherwise grounds for termination under the Sublicense Agreement, and in each case if so requested by BMS, procure the termination of the relevant Sublicense Agreement in accordance with its terms.
- (f) Nothing in this Sublicense Agreement will prohibit the Sublicensee from manufacturing and selling the Licensed Compound and Licensed Products in combination with other active pharmaceutical ingredients in the Territory, provided in each case that:
  - (i) the Sublicensee has the legal right to manufacture and sell such other active pharmaceutical ingredients in the applicable country within the Territory;
  - (ii) such manufacture and sale is in accordance with the licenses granted in this Sublicense Agreement; and
  - (iii) BMS and MPP do not provide the Sublicensee with any representations, warranties or other assurances about Combination Products that include the Licensed Compound or the Licensed Products, including with respect to patents owned by third parties.

#### **2.4 No trademark license**

- (a) No right or license, express or implied, is granted to the Sublicensee to use any trademark, trade name, trade dress or service mark owned or Controlled by BMS, MPP or any of their Affiliates.
- (b) The Sublicensee, at its sole cost and expense, will be responsible for the selection, registration and maintenance of all trademarks and trade dress which it employs in connection with its activities conducted pursuant to this Sublicense Agreement and will own and control such trademarks and trade dress.
- (c) The Sublicensee will not use the Product Trademark or any trademark or trade dress or product marking used by BMS or any of its Affiliates or licensees in any manner or any trademark or trade dress that is confusingly similar to the Product Trademark or any trademark or trade dress used by BMS or any of its Affiliates.
- (d) The Sublicensee will cause the color, markings and, with respect to Licensed Products in tablet form, shape of each Licensed Product to be distinctive from the BMS Product.
- (e) The Sublicensees will obtain the prior written approval, such approval not to be unreasonably withheld, of BMS for the Sublicensee's proposed trademark, trade dress or product markings or the color or shape of the Licensed Product. BMS will endeavor to provide its consent within 60 days of the Sublicensee's initial request (with a reminder being sent by the Sublicensee after 30 days), provided that if BMS does not provide any response within this 60 day period, the consent will be considered as accepted.

#### **2.5 No implied license**

No license or other right is or will be created or granted under this Sublicense Agreement by implication, estoppels or otherwise. All licenses and rights are or will be granted only as expressly provided in this Sublicense Agreement.

#### **2.6 Retained rights**

- (a) All rights not expressly granted under this Sublicense Agreement are reserved by BMS and may be used by BMS for any purpose.

- (b) Without limiting the foregoing, BMS retains any and all rights under the Licensed Patent Rights and Licensed Manufacturing Know-How to make, have made, use, offer for sale, sell, have sold, export or import:
  - (i) the Licensed Compound and products containing the Licensed Compound, including any Combination Products, for any use whether within or outside the Territory and whether within or outside the Field; and
  - (ii) compounds covered by one or more claims in the Licensed Patent Rights other than the Licensed Compound for any use.
- (c) BMS also expressly reserves and retains the right to make or have made, and use, the Licensed Compound and the Licensed Products for any internal research purpose.

#### 2.7 Product diversion

- (a) The Sublicensee acknowledges that the license to use and sell the Licensed Compound and Licensed Products granted under clause 2.1 is granted solely under and with respect to Licensed Patent Rights and Licensed Manufacturing Know-How for the purposes of supplying Licensed Products in the Field in the Territory.
- (b) Nothing in this Sublicense Agreement will be construed as granting the Sublicensee any rights under any patents, know-how or otherwise to use or sell the Licensed Compound or any Licensed Product for ultimate use outside of the Field and/or outside of the Territory.
- (c) For the avoidance of doubt, it would not be a breach of the Sublicense Agreement for the Sublicensee to manufacture or use the Licensed Compounds (in or outside of the Territory) for use, sale, or supply of such Licensed Compounds outside Territory where such use, sale or supply does not (i) infringe Licensed Patent Rights and Non-Territory Patent Rights; and (ii) rely on the Licensed Manufacturing Know-How. For the purposes of this provision, "to infringe" will mean the infringement of a patent in force, or any other activities that are prohibited under applicable laws in relation to Licensed Patent Rights and Non-Territory Patent Rights.
- (d) Without prejudice to clause 2.7(c), the Sublicensee will not, directly or indirectly, sell any Licensed Compound or Licensed Products to any Third Party if the Sublicensee has reason to believe that such Third Party may purchase such Licensed Compound or Licensed Products for ultimate use outside of the Territory.

#### 2.8 OFAC Licenses

- (a) Sublicensee represents that to its knowledge, neither Sublicensee nor any Affiliate, director, officer, or employee of Sublicensee, is a Sanctions Target.
- (b) Sublicensee agrees that it will not, with respect to the licensed intellectual property (including the Licensed Manufacturing Know-how), Licensed Compound and Licensed Products, engage in any transactions or dealings with or involving a Sanctions Target or a country or territory that is the target of US or EU country-wide or territory-wide Sanctions absent a license or other authorization from the relevant governmental authority, should such a license or other authorization be required. The Sublicensee shall convey such license or other authorization to the MPP and BMS, if required and obtained, prior to any such transactions or dealings.

Sublicensee also agrees that prior to, directly or indirectly,



- (i) making any Licensed Compound or any Licensed Product available to, or contracting for Product manufacture with, any Sanctions Target; or
- (ii) making any Licensed Compound or any Licensed Product available to, or contracting for Product manufacture in, a country or territory that is the target of country-wide or territory-wide Sanctions; it will obtain a license or other authorization, if required, either directly from the relevant government authority or cooperate with MPP and BMS to obtain such a license or other authorization in each case to permit Sublicensee to engage in transactions with a Sanctions Target or involving a country or territory that is the target of country-wide or territory-wide Sanctions; and

in the event that performance of this Sublicense Agreement by Sublicensee would (or might) in the reasonable opinion of BMS, breach, or expose BMS to potential liability under, any Sanctions or export control regime or any other similar laws of any jurisdiction (whether or not such Sanctions, controls or laws were in existence at the date of this Agreement and whether or not there have been any other changes in circumstance from those that existed at the date of this License Agreement or any Sublicense Agreement), BMS shall be entitled to immediately request that Sublicensee cease all shipments of Licensed Compound or Licensed Product into any country or territory that is the target of countrywide or territory-wide Sanctions, or if the Licensed Compound or Licensed Product is still within the custody and control of Sublicensee or its respective agents or representatives to use its best efforts to remove such Licensed Compound or Licensed Product from any country or territory that is the target of countrywide or territory-wide Sanctions, or suspending the operation of such provisions of the Sublicense Agreement (including supply provisions) which require or permit performance by any party where, in the reasonable opinion of BMS, such performance would result in a breach of, or expose BMS to potential liability under, any such Sanctions, controls or laws until, in the reasonable discretion of BMS, such time as all necessary approvals or licenses have been obtained to enable the Sublicense Agreement to continue in a lawful and compliant manner and without exposure to liability for BMS and, notwithstanding any provision of the Sublicense Agreement(s), BMS shall not be obliged to pay any compensation to the other party or otherwise indemnify the other party in respect of any losses or costs which that other party may suffer or incur as a result of such suspension and/or termination.

## **2.9 BMS Affiliates**

BMS is entering into this Sublicense Agreement for itself and its Affiliates. MPP and Sublicensee agree that BMS may enforce its rights, and perform its obligations, under this Sublicense Agreement through one or more of its Affiliates.

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## **3. ROYALTIES**

### **3.1 Royalties collection**

- (a) As a consideration for the sublicense granted to the Sublicensee under this Sublicense Agreement, the Sublicensee will be required to pay to MPP, for the duration of the Royalty Term, a royalty of 3% on the Net Sales of Licensed Products in the countries within Territory where Licensed Patents Rights are granted and in force. No royalties will be due by the Sublicensee for sales in those countries within the Territory in which BMS was not collecting royalties before the Effective Date from its own licensees in relation to the Licensed Patent Rights.



- (b) No royalties will be owed by the Sublicensee on sales of pediatric formulations Developed and sold by the Sublicensee.
- (c) Royalty payments will be payable to MPP by the Sublicensee on a product-by-product basis and country-by-country starting on the date of first commercial sale of a Licensed Product in the relevant country and continuing until the expiration of the last-to-expire Licensed Patent Rights that are granted and in force in such country (the **Royalty Term**). Royalties will be payable quarterly, 30 days following the end of every calendar quarter and be paid by way of bank transfer to MPP's designated bank account to be communicated to the Sublicensee.
- (d) Solely for the purpose of calculating Net Sales of Combination Products, if the Sublicensee sells Licensed Products in the form of a Combination Product in a particular country, Net Sales of such Combination Product in such country for the purpose of determining the royalty due to MPP will be calculated by multiplying actual Net Sales by the fraction "A/A+B", where:
  - (i) "A" is the fair market value of the portion of the Combination Product that contains the Licensed Compound; and
  - (ii) "B" is the fair market value of the portion of the Combination Product containing the other active pharmaceutical ingredient(s) or delivery device included the Combination Product,as such fair market values are determined by mutual agreement of MPP and the Sublicensees and is documented in writing.
- (e) The Sublicensees will be required to keep complete and accurate records of Licensed Compound and Licensed Products sold in sufficient detail to enable MPP to determine the amount of royalties due.

### 3.2 Use of royalties

- (a) MPP undertakes to distribute the amounts received as royalties from the Sublicensees to suitable community-based HIV organizations based in the country from which royalties were collected.
- (b) For the avoidance of doubt, BMS will not receive any royalties and will not be involved in the selection of such non-profit HIV activities.

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## 4. TECHNICAL ASSISTANCE

### 4.1 Documentation

- (a) BMS has provided or will provide the Sublicensee with one copy of all documents, data (including, but not limited to clinical data) or other information Controlled by BMS to the extent that such documents, data and information are the subject of the Licensed Manufacturing Know-How and are, in BMS's good faith judgment, reasonably necessary for the manufacture and registration (in the manner previously manufactured by or for BMS) of the Licensed Compound or a Licensed Product and are reasonably available to BMS without undue searching, provided however that the foregoing will in no event require BMS to provide copies of laboratory notebooks or manufacturing run records required to be maintained by BMS under applicable law. BMS will further provide the Sublicensee with NCE or other regulatory exclusivity waivers, as

applicable, to the extent required by the Regulatory Authorities for national registration in the Territory of the Licensed Products.

- (b) Such documentation will not be used by the Sublicensee for any purpose other than the manufacture and registration of the Licensed Compound and Licensed Products in accordance with this Sublicense Agreement and is Confidential Information of BMS. The Sublicensee will assume full responsibility and liability to BMS for any unauthorized use or disclosure of such Confidential Information.
- (c) BMS will be responsible for the cost of providing one set of copies only. In addition to paper and other tangible copies, BMS will, upon the Sublicensee's request and where reasonably available to BMS without undue searching, also provide to MPP electronic copies of such documents, data and other information; provided however that BMS will have no obligation to reformat or otherwise alter or modify any such materials in electronic form, in order to provide them to MPP. BMS will respond to reasonable requests from the Sublicensee for clarification on the information provided under this clause 4.1(c), where responses to such requests are, in BMS's good faith judgment reasonably necessary for the manufacture and registration (in the manner previously manufactured by or for BMS) of the Licensed Compound or a Licensed Product.
- (d) Any and all such materials delivered to the Sublicensee pursuant to this clause 4 are and will remain the sole property of BMS. BMS represents and warrants to the Sublicensee that the information provided to MPP pursuant to this clause 4 will be true, to the best of BMS's knowledge, as of the date of such documentation.

#### 4.2 Technical Transfer Package

- (a) The Sublicensee undertakes to accept the technical transfer package set out in Schedule F (the **Technical Transfer Package**) and relating to the Licensed Manufacturing Know-How.
- (b) The Sublicensee will evaluate the contents of the Technical Transfer Package with a view to taking a technical decision whether or not to use such contents in the manufacture of the Licensed Compound and Licensed Products. Irrespective of its decision whether to use the Technical Transfer Package or not, the Sublicensee should be in a position to make or have made generic equivalents of the Licensed Compound and the Licensed Products. In the event that it is alleged that the Sublicensee relied on the Licensed Manufacturing Know-How in breach of its obligations under this Sublicense Agreement or for purposes not contemplated in this Sublicense Agreement, the defenses set out in clause 11.1(b) will be available to the Sublicensee.

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#### 5. COMMERCIALIZATION

- (a) The Sublicensee will be responsible, at its own expense, for the conduct of all activities relating to the Commercialization of the Licensed Products in the Territory.
- (b) Each Licensed Product Commercialized by the Sublicensee under this Sublicense Agreement will be marked (to the extent not prohibited by law):
  - (i) with a notice that such Licensed Product is sold under a license from BMS and MPP; and
  - (ii) with all markings and notices as may be required by applicable law, including in relation to patent and other intellectual property.



- (c) The Sublicensee will use all reasonable efforts to provide an adequate supply of the Licensed Products (in all formulations and strengths) to meet the therapeutic needs in the Territory and will provide a strong supply network to support the distribution of the Licensed Products in the Territory. In recognition of the humanitarian objectives of this Sublicense Agreement, the Sublicensee also will use all reasonable efforts to promote the affordable access to the Licensed Products in the Territory.

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**6. MANUFACTURE AND SUPPLY**

- (a) The Sublicensee will be solely responsible at its expense for making or having made all of its respective requirements for the Licensed Compound and Licensed Products in conformity with all applicable specifications in the Territory and will hold all relevant authorizations and permits required in this respect.
- (b) The Sublicensee will use all reasonable commercial efforts to manufacture the Licensed Compound and Licensed Products for use and sale in the Territory consistent with this Sublicense Agreement and to provide a sufficient supply thereof to meet the needs in the Territory. The Sublicensee will, upon MPP's reasonable request, undertake to manufacture in sufficient volumes certain presentations and strengths of Licensed Products as listed in Schedule A.
- (c) In the event that MPP becomes aware of a tender for HIV/AIDS medicines that includes the Licensed Product and the presentations and strengths listed in Attachment A in the Territory, the Sublicensee will, upon MPP's reasonable request, submit a good faith proposal for such tender.
- (d) In the event that the Sublicensee becomes aware of a tender for HIV/AIDS medicines that includes the Licensed Product and the presentations and strengths listed in Attachment A in the Territory, the Sublicensee will consider to submit a good faith proposal for each such tender.

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**7. PHARMACOVIGILANCE AND QUALITY MATTERS**

**7.1 Pharmacovigilance**

- (a) If the Sublicensee becomes aware of any adverse reaction relating to the Licensed Compound or Licensed Products in connection with this Sublicense Agreement, the Sublicensee must inform BMS within 24 hours of its becoming aware and cooperate with BMS in fulfilling BMS's reporting responsibilities under applicable laws and regulations.
- (b) The Sublicensee will maintain effective and reliable systems for receiving and tabulating any reports of adverse reactions to the Licensed Products and to report such information on a timely basis to the relevant authorities and to BMS pursuant to the terms of this Sublicense Agreement.

**7.2 Quality**

The Sublicensees will manufacture the Licensed Compound and Licensed Products in a manner consistent with:

- (a) World Health Organization (WHO) pre-qualification standards; or
- (b) the standards of any Stringent Regulatory Authority, defined as regulatory authorities which are members, observers or associates of the International Conference of Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, as may be updated from time to time. Where such approvals are not yet

available, the Sublicensee will obtain temporary approval through a WHO Expert Review Panel, as appropriate and if applicable.

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**8. REPRESENTATIONS AND WARRANTIES**

**8.1 Representations, warranties and covenants of the Sublicensee**

- (a) The Sublicensee represents and warrants to BMS and MPP that:
- (i) the Sublicensee has all requisite corporate power and authority to enter into this Sublicense Agreement and to perform its obligations under this Sublicense Agreement;
  - (ii) the execution of this Sublicense Agreement and the performance by the Sublicensee of its obligations under this Sublicense Agreement have duly been authorized by all necessary action on behalf of the Sublicensee;
  - (iii) this Sublicense Agreement is legally binding and enforceable on the Sublicensee in accordance with its terms;
  - (iv) the performance of this Sublicense Agreement by the Sublicensee does not create a breach or default under any other agreement to which it is a party;
  - (v) the Sublicensee has capability and intent to manufacture the presentations and strengths of the Licensed Products MPP requires it to manufacture for ensuring access to appropriate and needed HIV formulations made possible through this Sublicense Agreement; and
  - (vi) it will comply with all applicable laws and regulations, including all applicable anti-bribery and corruption laws (including the U.S. Foreign Corrupt Practices Act and the UK Bribery Act 2010) and, in particular, the Sublicensee will not, directly or indirectly, offer, promise or give any financial or other advantage and or pay money or anything of value to government officials, political parties, candidates and any other person for the purposes of corruptly obtaining or retaining business; the Sublicensee will certify to BMS in writing, at the frequency requested by BMS (and at least once annually), compliance with their obligations under this Sublicense Agreement (including compliance with the U.S. Foreign Corrupt Practices Act and the UK Bribery Act 2010);
  - (vii) it will have and maintain suitable mechanisms in order to comply with all applicable laws (including the U.S. Foreign Corrupt Practices Act and the UK Bribery Act);
  - (viii) it will during the Term perform regular internal due diligence to ensure ongoing compliance with all applicable laws and the terms of this Sublicense Agreement.
- (b) The Sublicensee represents, warrants and covenants that all of its activities related to the use of the Licensed Patent Rights and Licensed Manufacturing Know-How and the Development and Commercialization of the Licensed Compound and Licensed Products pursuant to this Sublicense Agreement will comply with all applicable legal and regulatory requirements.
- (c) The Sublicensee further represents, warrants and covenants that it will not engage in any activities that use the Licensed Patent Rights and/or Licensed Manufactured Know-How in a manner that is outside the scope of the license rights granted to it under this Sublicense Agreement and that any modifications to the manufacturing process or

compound technology will be undertaken at the Sublicensee's sole risk and in no event will BMS or MPP indemnify, hold harmless or defend the Sublicensee for any such modifications.

- (d) The Sublicensee acknowledges and agrees that BMS or MPP will have no liability whatsoever in relation to any infringement of the intellectual property rights of any Third Party by the Sublicensee.

#### **8.2 As is license**

- (a) Notwithstanding any other provision of this Sublicense Agreement, the Sublicensee acknowledges and agrees that the Licensed Patent Rights and Licensed Manufacturing Know-How are licensed to Sublicensee "as is".
- (b) Notwithstanding any other provision of this Sublicense Agreement, BMS and MPP make no representation or warranty of non-infringement or any representation or warranty that the Licensed Patent Rights or Licensed Manufacturing Know-How is suitable for any purpose for which it may be used by the Sublicensee.

#### **8.3 Disclaimer**

- (a) BMS AND MPP MAKE NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE LICENSED PATENT RIGHTS OR LICENSED MANUFACTURING KNOW-HOW OR ANY LICENSE GRANTED BY MPP UNDER THIS SUBLICENSE AGREEMENT, OR WITH RESPECT TO ANY COMPOUNDS OR PRODUCTS, INCLUDING ANY COMBINATION PRODUCTS THAT INCLUDE THE LICENSED COMPOUND OR THE LICENSED PRODUCTS.
- (b) FURTHERMORE, NOTHING IN THIS SUBLICENSE AGREEMENT WILL BE CONSTRUED AS A REPRESENTATION OR WARRANTY THAT ANY PATENT OR OTHER PROPRIETARY RIGHTS INCLUDED IN THE LICENSED PATENT RIGHTS ARE VALID OR ENFORCEABLE OR THAT THE SUBLICENSEE'S USE OF THE LICENSED PATENT RIGHTS AND LICENSED MANUFACTURING KNOW-HOW CONTEMPLATED UNDER THIS SUBLICENSE AGREEMENT DOES NOT INFRINGE ANY PATENT RIGHTS OR OTHER INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

#### **8.4 Limitation of liability**

NOTWITHSTANDING ANYTHING IN THIS SUBLICENSE AGREEMENT OR OTHERWISE, IN RECOGNITION OF THE HUMANITARIAN NATURE OF THIS SUBLICENSE AGREEMENT AND THE LACK OF ANY ROYALTY TO BMS OR OTHER PAYMENTS TO BMS UNDER THIS SUBLICENSE AGREEMENT, BMS OR MPP WILL NOT HAVE ANY LIABILITY TO THE SUBLICENSEES FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL, PUNITIVE, EXEMPLARY OR INCIDENTAL DAMAGES RELATED TO THIS AGREEMENT, WHETHER UNDER CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY. IN PARTICULAR, AND WITHOUT LIMITING THE FOREGOING, BMS WILL HAVE NO LIABILITY IN THE EVENT THE LICENSED PATENT RIGHTS ARE INVALID OR UNENFORCEABLE, OR IN THE EVENT THE EXERCISE BY SUBLICENSEE OF ITS RIGHTS UNDER THIS SUBLICENSE AGREEMENT INFRINGES THE INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

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#### **9. INVENTIONS, PATENT MAINTENANCE, INFRINGEMENT**



## 9.1 Inventions

- (a) BMS (or its Affiliates) will own the entire right, title and interest in and to any and all inventions conceived solely by its employees and agents after the Effective Date relating to the Licensed Compound or any Licensed Product, including any adaptation of any manufacturing process or proprietary drug delivery or formulation technology of BMS or its Affiliates for the production of the Licensed Compound or any Licensed Product, and any patents covering such invention (**BMS Sole Inventions**), subject to the sublicense grant to the Sublicensee set out in clause 2.
- (b) The Sublicensee will own the entire right, title and interest in and to any and all inventions conceived solely by its employees and agents after the Effective Date relating to the Licensed Compound or any Licensed Product in the Field in the Territory (but only to the extent separable from BMS's intellectual property) (**Sublicensee Sole Inventions**). The Sublicensee will notify MPP and BMS in writing of any such invention and MPP and BMS will automatically have a non-exclusive, perpetual, worldwide, royalty-free license to use any such invention and any related intellectual property, irrespective of expiration or termination of this Sublicense Agreement. BMS may transfer or sublicense such inventions only to BMS's own Affiliates and suppliers, provided that such Affiliates and suppliers utilize such Sublicensee Sole Inventions solely for the benefit of BMS. Should MPP desire to sublicense any such rights to other sublicensees having entered into a sublicense agreement under the License Agreement in relation to the Licensed Product and Licensed Compound, the Sublicensee and MPP will enter into good faith negotiations.

## 9.2 Patent maintenance and abandonment

BMS will be responsible (at its own expense and discretion) for, and will control, the prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of all Licensed Patent Rights in the Territory.

## 9.3 Enforcement of Licensed Patent Rights

- (a) Information

In the event that MPP becomes aware of a suspected or actual breach of any Sublicense Agreement, MPP will notify BMS promptly, and following such notification, the Parties will confer.
- (b) Enforcement of Licensed Patent Rights

BMS (and/or its Affiliates) will have the right but will not be obligated, to bring an infringement action at its own expense, in its own name and entirely under its own direction and control, subject to the following:

  - (i) BMS, MPP and the Sublicensee will reasonably assist each other (at their own respective expense) in any action or proceeding being prosecuted if so requested by BMS, MPP and/or the Sublicensee, and such reasonable assistance is necessary for BMS, MPP and/or the Sublicensee to fully exercise its rights under such proceeding;
  - (ii) the Sublicensee will have the right to participate and be represented in any such suit by its own counsel at its own expense; and
  - (iii) no settlement of any such action or proceeding which restricts the scope, or adversely affects the enforceability, of a Licensed Patent Right may be entered

into by BMS without the prior written consent of MPP, which consent will not be unreasonably withheld, delayed or conditioned.

(c) **Infringement by the Sublicensee**

If the making, import, use, offer for sale or sale of the Licensed Compound or the Licensed Products by or on behalf of the Sublicensee infringe on the intellectual property rights of a Third Party in the Territory, the Sublicensee will be solely responsible for such infringement, and MPP and BMS will not have any obligation to defend or indemnify the Sublicensee with respect to any such claim.

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**10. AUDIT AND REPORTS**

**10.1 Reports**

The Sublicensee will send to MPP within 10 Business Days following the end of each calendar quarter the number of units of Licensed Products sold by strength / formulation by country and the amount of royalties payable and collected as a result of the sales thereof. The Sublicensee shall also provide MPP with a quarterly written report setting forth (a) Licensed Products in its development pipeline, (b) status of development of each Licensed Product in development, (c) regulatory filing plan for each Licensed Product, and (d) a list of countries within the Territory for which such regulatory approvals or authorizations have been obtained for any Licensed Product. The Sublicensee and MPP agree to confer on a quarterly basis regarding such reports and also review development and filing status of Licensed Products. MPP agrees that information contained in quarterly and other such reports shall be treated as Confidential Information.

**10.2 Audit**

- (a) The Sublicensee grants MPP and BMS the right, with reasonable notice, to:
  - (i) inspect and audit the performance of, and compliance with, this Sublicense Agreement and applicable laws, including the payment of the royalties by the Sublicensee; and
  - (ii) inspect and audit all documents and other records relating to the performance of this Sublicense Agreement.
- (b) BMS or MPP will nominate an independent third party auditor or consultant to exercise their respective rights set out in this clause 10.
- (c) The Sublicensee will cooperate with and provide all reasonable assistance to BMS and MPP, their officers, employees, agents, advisors, representatives or contractors exercising their rights under this clause 10.

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**11. NON DISCLOSURE OF CONFIDENTIAL INFORMATION**

**11.1 Non disclosure**

- (a) Each party agrees that, for so long as this Sublicense Agreement is in effect and for a period of 10 years thereafter, a Party receiving Confidential Information of another Party (or that has received any such Confidential Information from such other Party prior to the Effective Date) will:
  - (i) maintain in confidence such Confidential Information using not less than the efforts such Party uses to maintain in confidence its own proprietary industrial information of similar kind and value;

- (ii) not disclose such Confidential Information to any Third Party without the prior written consent of the relevant other Party, except for disclosure expressly permitted under this Sublicense Agreement; and
- (iii) not use such Confidential Information for any purpose except those permitted by this Sublicense Agreement (it being understood that this clause (iii) will not create or imply any rights or licenses not expressly granted under clause 2 of this Sublicense Agreement).

(b) **Exceptions**

The obligations under clause 11.1(a) will not apply with respect to any portion of the Confidential Information that the receiving Party can show by written evidence:

- (i) is publicly disclosed by the disclosing Party, either before or after it is disclosed to the receiving Party; or
- (ii) was known to the receiving Party or any of its Affiliates, without any obligations to keep it confidential or any restriction on its use, prior to disclosure by the disclosing Party; or
- (iii) is subsequently disclosed to the receiving Party or any of its Affiliates by a Third Party lawfully in the possession thereof and without any obligation to keep it confidential or any restriction on its use; or
- (iv) is published by a Third Party or otherwise becomes publicly available, either before or after it is disclosed to the receiving Party; or
- (v) has been independently developed by employees or contractors of the receiving Party or any of its Affiliates without the aid, application or use of Confidential Information of the disclosing Party.

**11.2 Authorized disclosure**

- (a) The receiving Party may disclose Confidential Information belonging to another Party to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:
  - (i) regulatory filings;
  - (ii) prosecuting or defending litigation;
  - (iii) complying with applicable governmental laws and regulations (including the rules and regulations of the Securities and Exchange Commission or any national securities exchange) and with judicial process, if in the reasonable opinion of the receiving Party's counsel, such disclosure is necessary for such compliance; and
  - (iv) disclosure, in connection with the performance of this Sublicense Agreement and solely on a "need-to-know basis", to Affiliates, potential collaborators (including potential co-marketing and co-promotion contractors), research collaborators, employees, consultants or agents, each of whom prior to disclosure must be bound by similar obligations of confidentiality and non-use at least equivalent in scope to those set forth in this clause 10; provided however that the receiving Party will remain responsible for any failure by any such Person who receives Confidential Information pursuant to this clause 10 to treat such Confidential Information as required under this clause 10.



- (b) If and whenever any Confidential Information is disclosed in accordance with this clause 11.2, such disclosure will not cause any such information to cease to be Confidential Information except to the extent that such disclosure results in a public disclosure of such information (otherwise than by breach of this Sublicense Agreement). Where reasonably possible, the receiving Party will notify the disclosing Party's intent to make such disclosure pursuant to this clause 11.2 sufficiently prior to making such disclosure so as to allow the disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information.
- (c) The Parties agree that a copy of this Sublicense Agreement may be publicly disclosed on MPP's website. Such disclosure will not constitute a breach of the Parties obligations under this clause 11.

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## **12. INDEMNITY**

### **12.1 Sublicensee indemnity**

The Sublicensee will indemnify, defend and hold harmless BMS, MPP and their respective Affiliates, and their respective officers, directors, employees, agents, licensors and their respective successors, heirs and assigns and representatives, from and against any and all claims, threatened claims, damages, losses, suits, proceedings, liabilities, costs (including reasonable legal expenses, costs of litigation and reasonable attorney's fees) or judgments, whether for money or equitable relief, of any kind (**Losses and Claims**) arising out of or relating, directly or indirectly:

- (a) any breach by the Sublicensee of any of the provisions of this Sublicense Agreement;
- (b) any negligence or willful misconduct by or on behalf of the Sublicensee;
- (c) the Sublicensee's (or its Affiliates) use and practice otherwise of the Licensed Patent Rights and Licensed Manufacturing Know-How, including claims and threatened claims based on:
  - (i) product liability, bodily injury, risk of bodily injury, death or property damage;
  - (ii) infringement or misappropriation of Third Party patents, copyrights, trademarks or other intellectual property rights; or
  - (iii) the failure to comply with applicable laws related to the matters referred to in the foregoing with respect to the Licensed Compound and/or any Licensed Product except in any such case for Losses and Claims to the extent resulting from the gross negligence, recklessness or willful misconduct of BMS or MPP.

### **12.2 Insurance**

The Sublicensee agrees to purchase and maintain appropriate insurance in order to cover its product liability insurance related to the Licensed Compound and Licensed Products.

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## **13. TERM AND TERMINATION**

### **13.1 Term**

This Sublicense Agreement will commence as of the Effective Date and, unless sooner terminated in accordance with the terms of this Sublicense Agreement or by mutual written consent, will expire upon the expiration of the last-to-expire of the Licensed Patent Rights.

### **13.2 Termination by any Party**



Any of the Parties will have the right to terminate this Sublicense Agreement, at its sole discretion, upon delivery of written notice to the other Parties, upon the occurrence of any of the following:

- (a) one of the other Parties becomes bankrupt, insolvent or cannot pay its debts when due;
- (b) a material breach of this Sublicense Agreement by another Party that is not cured within 90 days after written notice of such breach is given.

### **13.3 Additional termination rights**

BMS and MPP will each have the right to terminate this Sublicense Agreement upon delivery of written notice to Sublicensee upon the occurrence of any of the following:

- (a) the failure of Sublicensee to comply with MPP's reasonable requests under clauses 6(b) through (d) of this Sublicense Agreement;
- (b) any failure by the Sublicensee of ensuring compliance with relevant OFAC regulations under clause 2.8 of this Sublicense Agreement;
- (c) the occurrence of any material safety issue that BMS or MPP reasonably believes makes it inadvisable to proceed or continue with the commercialization of the Licensed Product in the Territory;
- (d) without prejudice to clause 2.7(c), a cross border diversion of the Licensed Products whereby any Sublicensee (directly or indirectly or through a Third Party, located in or out of the Territory) uses, offers for sale, sells, has sold Licensed Products for use in any country outside of the Territory;
- (e) any failure by the Sublicensees to comply with the quality requirements under clause 7.2 of this Sublicense Agreement;
- (f) the failure by the Sublicensees to Develop and Commercialize the Licensed Products in the formulation and strengths listed in Schedule A within three years of the effective date of the Sublicense Agreement;
- (g) the occurrence of a direct or indirect Change of Control of Sublicensee that has not been consented to by BMS and MPP in writing;
- (h) in the event of any serious or intentional violation of any laws and regulations or misappropriation of a Third Party's intellectual property rights by the Sublicensee anywhere in the world, which in BMS's and MPP's judgment, may reflect unfavorably on BMS, MPP, their reputation or the Licensed Products.

### **13.4 Scope of termination**

Except as otherwise expressly provided in this Sublicense Agreement, any termination of this Sublicense Agreement pursuant to this clause 13 will be as to all Licensed Compounds and Licensed Products.

### **13.5 Effect of termination**

- (a) Upon termination of this Sublicense Agreement other than as a result of expiration pursuant to clause 13.1 of this Sublicense Agreement:
  - (i) all rights and licenses granted to Sublicensee under clause 2 will terminate, and all rights, licenses and cross-references will revert to BMS and MPP will cease



all use of the Licensed Patent Rights and the Licensed Manufacturing Know-How;

- (ii) none of the Parties will be relieved of any obligation that accrued prior to the effective date of such termination.
- (b) Upon termination of the License Agreement between BMS and MPP other than as a result of expiration pursuant to clause 13.1 of the License Agreement, this Sublicense Agreement will be automatically be converted into a license between BMS and the Sublicensee, provided that BMS reserves its rights to terminate the license so converted on the same grounds as those having led to termination of the License Agreement;
- (c) It is understood and agreed that BMS and MPP will be entitled to specific performance as a remedy to enforce the provisions of this clause 13.5, in addition to any other remedy to which it may be entitled by applicable law.
- (d) Termination of this Sublicense Agreement by BMS or MPP will not preclude BMS and/or MPP from claiming damages from the Sublicensee for any breach of this Sublicense Agreement or in relation to the event having given rise to the termination, or affect any other right or remedy available to BMS and MPP.

#### **13.6 Survival**

The following provisions will survive termination or expiration of this Sublicense Agreement, as well as any other provisions which by their nature are intended to survive termination or expiration: clause 1 (as applicable), clauses 8.3, 8.4, 11, 12, 13.6, 13.7, 14 and 15.

#### **13.7 Termination cooperation**

Upon the termination or expiration of this Sublicense Agreement, the Parties will cooperate with one another to provide for an orderly wind-down of the transactions contemplated in this Sublicense Agreement.

#### **13.8 Bankruptcy**

The Parties agree that in the event a Party becomes a debtor under Title 11 of the U.S. Code, this Sublicense Agreement will be deemed to be, for the purposes of Section 365(n) of such title, a license to rights to "intellectual property" as defined therein. Each party as a licensee hereunder will have the rights and elections as specified in such Title 11. Any agreements supplemental to this Sublicense Agreement will be deemed to be "agreements supplementary to" this Sublicense Agreement for the purposes of Section 365(n) of such Title 11.

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### **14. DISPUTE RESOLUTION**

#### **14.1 Resolution by senior executives**

- (a) Except as provided in clause 14.2(h), all disputes, controversies or claims between the Parties in connection with this Sublicense Agreement, its construction, or the rights, duties or liabilities of either Party under this Sublicense Agreement (a "**Dispute**") must be resolved pursuant to the following resolution process in this clause 14.1 and the arbitration process in clause 14.2. The parties to any such Dispute may alter or amend these procedures by agreement in writing.
- (b) To commence the resolution process, any Party may serve a notice on another Party identifying: (i) the nature of the Dispute; and (ii) the amount in Dispute.
- (c) Once notice is received, the parties must first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves.



- (d) In the event that such Dispute is not resolved on an informal basis within 30 days after such notice is received, either Party may, by written notice to the other Party, refer the Dispute to the Executive Director of MPP, to BMS's Executive Director Global Commercial Lead HIV Portfolio and to Sr. V.P. - GFOD of the Sublicensee (together, the **Designated Officers**) for attempted resolution by good faith negotiation.
- (e) If any such Dispute is not resolved by the Designated Officers within 30 days after the receipt of the notice referring such Dispute to the Designated Officers, then either Party may demand resolution of the Dispute by binding arbitration pursuant to clause 14.2.

#### **14.2 Arbitration**

Except as provided in clause 14.2(h), if any Dispute is not resolved in accordance with clause 14.1, then either Party may submit such Dispute for resolution through binding arbitration as follows:

- (a) A Party may submit such Dispute to arbitration by notifying the other Party in writing and demanding arbitration of such Dispute in accordance with this clause 14.2. Any such Dispute will be finally resolved under the Rules of Arbitration of the International Chamber of Commerce (the **ICC**), except as provided herein.
- (b) Within 30 days after receipt of such notice, the Parties will each designate in writing an arbitrator, and within 30 days those arbitrators shall designate a third arbitrator to resolve the Dispute provided however that if the Parties cannot agree on an arbitrator within such 30 day period, the arbitrator will be selected by the ICC. In the event that there are more than two Parties that are parties to the arbitration proceedings, where there are multiple claimants or multiple respondents, the multiple claimants, jointly, and the multiple respondents, jointly, shall designate an arbitrator. The arbitrators will be persons knowledgeable and experienced in the law concerning the subject matter of the dispute, and will not be a current or former Affiliate, employee, consultant, officer, director of either Party or a stockholder of either Party, or otherwise have any current or previous relationship with either Party or their respective Affiliates and will not be a resident or citizen of the Territory. The governing law of this Sublicense Agreement will govern any such proceedings. The language of the arbitration will be English.
- (c) Within 30 days after the designation of the third arbitrator, the arbitrators and the Parties will meet, and each Party will provide to the arbitrators a written summary of all disputed issues, such Party's position on such disputed issues and such Party's proposed ruling on the merits of each such issue.
- (d) The arbitrators will set a date for a hearing, which will be no later than 30 days (or such longer period agreed in writing by the Parties) after the submission of written proposals pursuant to clause 14.2(b), for the presentation of evidence and legal argument concerning each of the issues identified by the Parties. The Parties will have the right to be represented by counsel. Except as provided in this Sublicense Agreement, the arbitration will be governed by the Rules of Arbitration of the ICC pursuant to clause 14.2(a) (the **Rules**).
- (e) The arbitrators will each use his or her best efforts to rule on each disputed issue within 30 days (or such longer period agreed in writing by the Parties) after completion of the hearing described in clause 14.2(d). The determination of the arbitrator as to the resolution of any dispute will be binding and conclusive upon all Parties. All rulings of the arbitrator will be in writing and will be delivered to the Parties except to the extent the Rules provide otherwise. Nothing contained herein will be construed to permit the arbitrator to award punitive, exemplary or any similar damages.



- (f) The attorney's fees of the Parties in any arbitration, fees of the arbitrator and costs and expenses of the arbitration will be borne by the Parties in a proportion determined by the arbitrator.
- (g) Any arbitration pursuant to this clause 14.2 will be conducted in Paris, France. The parties agree that any proceeding initiated to enter or confirm any arbitration award may be entered in and enforced by any court with jurisdiction, including a court sitting in New York City, New York. In this respect the Parties irrevocably and unconditionally consent to the exercise of personal jurisdiction by the courts in New York in such proceedings.
- (h) The Parties acknowledge and agree that the breach by any Party of the provision of this Sublicense Agreement related to the protection of trade secrets or confidentiality would not be fully compensable by money damages and would result in irreparable harm to the other Party. Notwithstanding anything in this clause 14, each Party will have the right to seek injunctive or other equitable relief from a court of competent jurisdiction as may be necessary to avoid irreparable harm, maintain the status quo or preserve the subject matter of the arbitration, including any breach or threatened breach of clauses 11.1 and 13.5. The parties agree that any such request for injunctive or equitable relief may be brought in a court sitting in New York City, New York and the Parties irrevocably and unconditionally consent to the exercise of personal jurisdiction by the courts in New York in such proceedings.

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**15. MISCELLANEOUS**

**15.1 Agreement management**

- (a) At the Commencement Date, each party will appoint an individual as **Agreement Manager**. Each party may update the identity of its Agreement Manager during the Term by notice in writing to the other Parties.
- (b) The Agreement Managers of each Party will meet in person or discuss via teleconference at least once a quarter during the Term to discuss performance of each party's obligations under this Sublicense Agreement and any other matters as notified by another Party in advance of such meeting.

**15.2 Severability**

If any one or more of the provisions of this Sublicense Agreement is held to be invalid or unenforceable, the provision will be considered severed from this Sublicense Agreement and will not serve to invalidate any remaining provisions of this Sublicense Agreement. The Parties will make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Sublicense Agreement may be realized.

**15.3 Notices**

- (a) Any notice required or permitted to be given under this Sublicense Agreement will be in writing and will be delivered by hand or overnight courier with tracking capabilities or mailed postage prepaid by first class, registered or certified mail addressed as set forth below unless changed by notice so given:

- (i) If to BMS:

Bristol-Myers Squibb Company  
345 Park Avenue  
New York, NY 10154



U.S.A.  
Attention: General Counsel and Corporate Secretary

with a copy to:

Bristol Myers Squibb Company  
777 Scudders Mill Road  
Plainsboro, NJ 08536  
U.S.A.

Attention: Vice President and Assistant General Counsel, Strategic Corporate Transactions

(ii) If to MPP:

The Medicines Patent Pool Foundation  
Rue de Varembe 7  
Geneva 1202  
Switzerland  
Attention: General Counsel

(iii) If to the Sublicensee:

Aurobindo Pharma Ltd.  
3<sup>rd</sup> Floor, Watermark Building  
Whitefield, Kandaour, Hitech City  
Hyderabad – 084 Telangana, India  
Attention: G. P. Prasad

- (b) Any such notice will be deemed delivered on the date received. A Party may add, delete, or change the person or address to whom notices should be sent at any time upon written notice delivered to the Party's notices in accordance with this clause 15.3.

**15.4 Force Majeure**

- (a) No party will be liable for any failure to perform its obligations under this Sublicense Agreement (other than obligations to make payments of money) to the extent such performance has been delayed, interfered with or prevented by any event of Force Majeure.
- (b) As used in this Sublicense Agreement, **Force Majeure** means any circumstances whatsoever which are not within the reasonable control of the Party affected thereby, including an act of God, war, terrorism, insurrection, riot, strike or labor dispute, shortage of materials, fire, explosion, flood, government requisition or allocation, breakdown of damage to plant, equipment or facilities, interruption or delay in transportation, fuel supplies or electrical power, embargo, boycott, order or act of civil or military authority. The Party who declares an event of Force Majeure will give prompt notice to the other Parties of such declaration.
- (c) If the performance of any obligation has been delayed, interfered with or prevented by an event of Force Majeure, then the Party affected by such event will take such actions as are reasonably available to remove the event of Force Majeure or to mitigate the effect of such occurrence, except that labor disputes will be settled at the sole discretion of the Party affected thereby.
- (d) If an event of Force Majeure occurs, the obligations of the Parties under this Sublicense Agreement (other than the obligations to make payments of money) will be suspended during, but not longer than, the continuance of the event of Force Majeure.



### 15.5 Assignment

- (a) None of the Parties may assign this Sublicense Agreement, except as specifically permitted by this clause 15.5.
- (b) BMS may, without MPP's or the Sublicensee's consent, assign or transfer any and all of its rights and obligations under this Sublicense Agreement to any Affiliate of BMS or to any Third Party (including a successor in interest), provided however that such assignee or transferee agrees in a writing provided to MPP and to the Sublicensee to assume such transferred obligations and to be bound by the terms of this Sublicense Agreement. In the event of any such transfer of any or all of BMS's obligations under this Sublicense Agreement (or any or all of the obligations of any BMS Affiliate to which any of such obligations may have been transferred) to a Third Party, the assumption of such transferred obligations by such Third Party will constitute the release of BMS and its Affiliates from such obligations, and thereafter BMS and its Affiliates will have no further liability or responsibility to MPP, the Sublicensee and their Affiliates to which any of such obligations may have been transferred, the assumption or guarantee by such Third Party of the obligations under this Sublicense Agreement of such transferred BMS Affiliate will constitute the release of BMS from such obligations, and thereafter BMS will have no further liability or responsibility to MPP, the Sublicensee and its Affiliates in respect of such obligations.
- (c) The Sublicensee may not assign all or any part of its rights, or delegate all or any part of its obligations, under this Sublicense Agreement without BMS's and MPP's prior written consent.
- (d) MPP may not assign all or any part of its rights, or delegate all or any part of its obligations, under this Sublicense Agreement without BMS's prior written consent.
- (e) Any assignment or transfer in violation of the foregoing will be null and void and wholly invalid, the assignee or transferee in any such assignment or transfer will acquire no rights whatsoever, and the non-assigning non-transferring Party will not recognize, nor will it be required to recognize, such assignment or transfer.
- (f) Subject to the foregoing provisions of clause 15.5, this Sublicense Agreement will inure to the benefit of and be binding on the Parties' successors and assigns.

### 15.6 Waiver and modifications

The failure of any Party to insist on the performance of any obligation under this Sublicense Agreement will not be deemed to be a waiver of such obligation. Waiver of any breach of any provision of this Sublicense Agreement will not be deemed to be a waiver of any other breach of such provision or any other provision on such occasion or any succeeding occasion. No waiver, modification, release or amendment of any obligation under or provision of this Sublicense Agreement will be valid or effective unless in writing and signed by all Parties.

### 15.7 Choice of law

This Sublicense Agreement will be governed, and will be construed in accordance with the laws of England without regard to its conflicts of law provisions.

### 15.8 Publicity

The Parties agree that no Party will issue a press release or public announcement concerning the transactions contemplated by this Sublicense Agreement without the advance written consent of the other Parties. If a Party intends to issue a press release, it will submit a draft of such proposed press release to the other Parties at least 5 Business Days prior to the date such Party

intends to issue the release and will agree to consider the comments of the other Parties to the press release. After any initial press release or public announcement is made, however, each Party may disclose to third parties or make public statements, by press release or otherwise, regarding the existence of this Sublicense Agreement, the identity of the parties, and terms, conditions and subject matter previously disclosed about the Sublicense Agreement, provided such disclosures or statements are accurate and complete with respect to the subject matter thereof and the information disclosed therein.

**15.9 Relationship of the Parties**

Each Party is an independent contractor under this Sublicense Agreement. Nothing contained in this Sublicense Agreement is intended or is to be construed so as to constitute BMS, MPP and the Sublicensee as partners, agent or joint venturers. None of the Parties will have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Parties or to bind the other Parties to any contract, agreement or undertaking with any Third Party.

**15.10 Headings**

Headings and captions are for convenience only and are not to be used in the interpretation of this Sublicense Agreement.

**15.11 Entire Agreement**

This Sublicense Agreement constitutes the entire agreement between the Parties as to the subject matter of this Sublicense Agreement, and supersedes and merges all prior negotiations, representations, agreements and understandings regarding the same.

**15.12 Counterparts**

This Sublicense Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts will be deemed an original, will be construed together and will constitute one and the same instrument.

**15.13 Ambiguities**

Each of the Parties acknowledges and agrees that this Sublicense Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained in this Sublicense Agreement, including the language whereby it has been expressed, represents the joint efforts of the Parties and their counsel. Accordingly, in interpreting this Sublicense Agreement or any provision hereof, no presumption will apply against any Party as being responsible for the wording or drafting of this Sublicense Agreement or any such provision, and ambiguities, if any, in this Sublicense Agreement will not be construed against any Party irrespective of which Party may be deemed to have authored the ambiguous provisions.

**15.14 Business conduct and ethics**

BMS takes seriously its compliance and ethics responsibilities and seeks to do business only with third parties who share our high standards of ethical behavior. To that end, BMS has adopted Standards of Business Conduct and Ethics for Third Parties (**3P Standards**). BMS encourages MPP and the Sublicensee to comply with the elements of the 3P Standards that apply to them. For your reference, the 3P Standards are available at [http://www.bms.com/ourcompany/compliance\\_ethics/Pages/default.aspx](http://www.bms.com/ourcompany/compliance_ethics/Pages/default.aspx).

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IN WITNESS WHEREOF the Parties have caused this Sublicense Agreement to be executed by their respective duly authorized officers.

For an on behalf of  
Bristol-Myers Squibb Company:

  
Signature

Name: SUNIL R. PATEL

Title: HEAD, INT'L POLICY & GOVT AFFAIRS

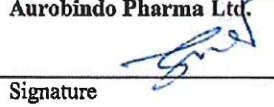
For an on behalf of  
The Medicines Patent Pool Foundation:

  
Signature

Name: Greg Pany

Title: Executive Director

For an on behalf of  
Aurobindo Pharma Ltd.

  
Signature

Name: Mr. G.P. Prasad

Title: Sr. Vice President  
- G.P.O.D





**Schedule A      Licensed Compound, presentations and strengths**

**Licensed Compound**

The compound known as "atazanavir".

**Presentations and strengths**

Capsules in 150 mg, 200 mg, 300 mg strengths containing atazanavir as its sole active ingredient and any additional formulation or strength (including pediatric formulations) for which BMS would receive FDA approval in relation to the Licensed Compound during the Term.

A handwritten signature in blue ink, appearing to be "BMS", is located in the center of the page.

## Schedule B      Licensed Patent Rights

The list below is accurate to the best of BMS knowledge as of the Effective Date. BMS has no obligation to update this list of the Licensed Patent Rights. It remains the responsibility of MPP and the Sublicensee to check for any changes in status.

### Title: PROCESS FOR PREPARING ATAZANAVIR BISULFATE AND NOVEL FORMS

Country	Appln. No.	Filing Date	Patent No.	Grant Date
India	02933/DELNP/09	01 mai 2009		
India	06425/DELNP/2006	03 mai 2005		
South Africa	2006/9084	03 mai 2005	2006/9084	27 août 2008

### Title: TABLETED COMPOSITIONS CONTAINING ATAZANAVIR

Country	Appln. No.	Filing Date	Patent No.	Grant Date
India	8328/DELNP/2009	20 juin 2008		

### Title: TABLETED COMPOSITIONS CONTAINING ATAZANAVIR

Country	Appln. No.	Filing Date	Patent No.	Grant Date
India	8332/DELNP/2009	20 juin 2008		

### Title: TABLETED COMPOSITIONS CONTAINING ATAZANAVIR

Country	Appln. No.	Filing Date	Patent No.	Grant Date
India	08330/DELNP/09	20 juin 2008		

### Title: ATAZANAVIR SULFATE FORMULATIONS WITH IMPROVED pH EFFECT

Country	Appln. No.	Filing Date	Patent No.	Grant Date
India	9097/CHENP/12	07 avr 2011		

### Title: A PROCESS FOR THE PREPARATION OF ALPHA' CHLOROKETONES

Country	Appln. No.	Filing Date	Patent No.	Grant Date
India	145/MUMNP/2003	20 juil 2001	214096	05 oct 2007

### Title: STEREOSELECTIVE REDUCTION OF SUBSTITUTED OXO-BUTANES

Country	Appln. No.	Filing Date	Patent No.	Grant Date
India	93/MUMNP/2003	20 juil 2001	206217	19 avr 2007

### Title: BMS-232632 HIV PROTEASE INHIBITOR - ATAZANAVIR

Country	Appln. No.	Filing Date	Patent No.	Grant Date
India	310/CHE/2007	14 févr 2007		
India	3234/CHE/2008	22 déc 2008		
India	3235/CHE/2008	22 déc 2008		
Pakistan	226/97	15 avr 1997	141049	20 déc 2010
Pakistan	717/2009	03 août 2009	141065	20 déc 2010
South Africa	97/3387	21 avr 1997	97/3387	31 déc 1997



**Title: BISULFATE SALT OF HIV PROTEASE INHIBITOR**

<b>Country</b>	<b>Appln. No.</b>	<b>Filing Date</b>	<b>Patent No.</b>	<b>Grant Date</b>
Ecuador	SP992834	19 janv 1999		
Georgia	AP1998004009	22 déc 1998	P3026	25 juil 2003
Pakistan	12/99	07 janv 1999	136678	07 mai 2001
South Africa	990056	05 janv 1999	990056	27 sept 2000





### Schedule C      Non-Territory Patent Rights

The list below is accurate to the best of BMS knowledge as of the Effective Date. BMS has no obligation to update this list of the Non-Territory Patent Rights. It remains the responsibility of MPP and the Sublicensee to check for any changes in status.

**Title: PROCESS FOR PREPARING ATAZANAVIR BISULFATE AND NOVEL FORMS**

Country	Appln. No.	Filing Date	Patent No.	Grant Date
Argentina	P050101776	03 mai 2005		
Australia	2010201538	16 avr 2010		
Australia	2005240622	03 mai 2005	2005240622	27 mai 2010
Brazil	PI0509595.6	03 mai 2005		
Canada	2777216	03 mai 2005		
Canada	2565629	03 mai 2005	2565629	31 juil 2012
Chile	1057/05	04 mai 2005		
Chile	1057/05	04 mai 2005		
Chile				
China	200910145402.X	18 mai 2009	200910145402.X	14 déc 2011
China	200580022550.2	03 mai 2005	200580022550.2	30 mars 2011
European (Patents)	Procedure 05744537.1	03 mai 2005		
European (Patents)	Procedure 05744537.1	10 juil 2013		
European (Patents)	Procedure 13175944.1	10 juil 2013		
Hong Kong	07103668.8	10 avr 2007		
Israel	178965	03 mai 2005	178965	01 sept 2011
Japan	2007-511502	03 mai 2005	5086069	14 sept 2012
South Korea	10-2006-7025370	03 mai 2005	10-1153606	30 mai 2012
Mexico	PA/A/06/012612	03 mai 2005	274189	19 févr 2010
Norway	20065441	03 mai 2005		
Peru	000500/2005-OIN	04 mai 2005		
Russian Federation	2006142768	03 mai 2005	2385325	27 mars 2010
Singapore	200607509.7	03 mai 2005	127083	14 janv 2011
Taiwan	94114255	03 mai 2005		
United States Of America	12/360468	27 janv 2009	7838678	23 nov 2010
United States Of America	12/900588	08 oct 2010	8513428	20 août 2013
United States Of America	11/119558	02 mai 2005	7829720	09 nov 2010
Venezuela	VN05/000854	04 mai 2005		
International Procedure	PCT/US2005/015333	03 mai 2005		

**Title: A PROCESS FOR PREPARING (2R,3S)-1,2-EPOXY-3-(PROTECTED)AMINO-4-SUBSTITUTED BUTANE**

Country	Appln. No.	Filing Date	Patent No.	Grant Date
Argentina	P060102134	23 mai 2006		



Germany	06750625.3	19 avr 2006	1893765	30 nov 2011
European (Patents)	Procedure 06750625.3	19 avr 2006	1893765	30 nov 2011
Spain	06750625.3	19 avr 2006	1893765	30 nov 2011
France	06750625.3	19 avr 2006	1893765	30 nov 2011
United Kingdom	06750625.3	19 avr 2006	1893765	30 nov 2011
Italy	06750625.3	19 avr 2006	1893765	30 nov 2011
United States Of America	12/506596	21 juil 2009	8119389	21 févr 2012
United States Of America	11/365275	01 mars 2006	7582468	01 sept 2009
International Procedure	PCT/US2006/014629	19 avr 2006		

**Title: TABLETED COMPOSITIONS CONTAINING ATAZANAVIR**

Country	Appl. No.	Filing Date	Patent No.	Grant Date
Australia	2008268625	20 juin 2008		
European (Patents)	Procedure 08771562.9	20 juin 2008		
Gulf Cooperation Council	11117	22 juin 2008		
Japan	2010-513431	20 juin 2008		
South Korea	2009-7026607	20 juin 2008		
Lebanon	8336	13 juin 2008	8336	23 juil 2009
Mexico	MX/A/09/013504	20 juin 2008	312207	12 août 2013
Thailand	0801003176	20 juin 2008		
United States Of America	13/906651	31 mai 2013		
International Procedure	PCT/US2008/067622	20 juin 2008		

**Title: TABLETED COMPOSITIONS CONTAINING ATAZANAVIR**

Country	Appl. No.	Filing Date	Patent No.	Grant Date
Austria	08771569.4	20 juin 2008	2178513	30 mars 2011
Australia	2008268537	20 juin 2008	2008268537	14 févr 2013
Belgium	08771569.4	20 juin 2008	2178513	30 mars 2011
Bulgaria	08771569.4	20 juin 2008	2178513	30 mars 2011
Switzerland	08771569.4	20 juin 2008	2178513	30 mars 2011
Cyprus (Republic)	08771569.4	20 juin 2008	2178513	30 mars 2011
Czech Republic	08771569.4	20 juin 2008	2178513	30 mars 2011
Germany	08771569.4	20 juin 2008	2178513	30 mars 2011
Denmark	08771569.4	20 juin 2008	2178513	30 mars 2011
Estonia	08771569.4	20 juin 2008	2178513	30 mars 2011
European Procedure (Patents)	08771569.4	20 juin 2008	2178513	30 mars 2011
Spain	08771569.4	20 juin 2008	2178513	30 mars 2011
Finland	08771569.4	20 juin 2008	2178513	30 mars 2011
France	08771569.4	20 juin 2008	2178513	30 mars 2011
United Kingdom	08771569.4	20 juin 2008	2178513	30 mars 2011
Greece	08771569.4	20 juin 2008	2178513	30 mars 2011

Croatia	08771569.4	20 juin 2008	2178513	30 mars 2011
Hungary	08771569.4	20 juin 2008	2178513	30 mars 2011
Ireland	08771569.4	20 juin 2008	2178513	30 mars 2011
Iceland	08771569.4	20 juin 2008	2178513	30 mars 2011
Italy	08771569.4	20 juin 2008	2178513	30 mars 2011
South Korea	2009-7026604	20 juin 2008		
Lithuania	08771569.4	20 juin 2008	2178513	30 mars 2011
Luxembourg	08771569.4	20 juin 2008	2178513	30 mars 2011
Latvia	08771569.4	20 juin 2008	2178513	30 mars 2011
Monaco	08771569.4	20 juin 2008	2178513	30 mars 2011
Malta	08771569.4	20 juin 2008	2178513	30 mars 2011
Mexico	MX/A/09/013461	20 juin 2008	290355	22 sept 2011
Netherlands	08771569.4	20 juin 2008	2178513	30 mars 2011
Norway	08771569.4	20 juin 2008	2178513	30 mars 2011
Poland	08771569.4	20 juin 2008	2178513	30 mars 2011
Portugal	08771569.4	20 juin 2008	2178513	30 mars 2011
Romania	08771569.4	20 juin 2008	2178513	30 mars 2011
Sweden	08771569.4	20 juin 2008	2178513	30 mars 2011
Slovenia	08771569.4	20 juin 2008	2178513	30 mars 2011
Slovakia	08771569.4	20 juin 2008	2178513	30 mars 2011
Thailand	0801003177	20 juin 2008		
Turkey	08771569.4	20 juin 2008	2178513	30 mars 2011
United States Of America	12/664802	20 juin 2008		

International Procedure PCT/US2008/067633 20 juin 2008

**Title: TABLETED COMPOSITIONS CONTAINING ATAZANAVIR**

Country	Appln. No.	Filing Date	Patent No.	Grant Date
Germany	08771565.2	20 juin 2008	2178512	09 mars 2011
European Procedure (Patents)	08771565.2	20 juin 2008	2178512	09 mars 2011
Spain	08771565.2	20 juin 2008	2178512	09 mars 2011
France	08771565.2	20 juin 2008	2178512	09 mars 2011
United Kingdom	08771565.2	20 juin 2008	2178512	09 mars 2011
Italy	08771565.2	20 juin 2008	2178512	09 mars 2011
Japan	2010-513435	20 juin 2008		
South Korea	2009-7026606	20 juin 2008		
Mexico	MX/A/09/013499	20 juin 2008	290480	26 sept 2011
Thailand	0801003178	20 juin 2008		
International Procedure	PCT/US2008/067629	20 juin 2008		

**Title: ATAZANAVIR SULFATE FORMULATIONS WITH IMPROVED pH EFFECT**

Country	Appln. No.	Filing Date	Patent No.	Grant Date
China	201180028213.X	07 avr 2011		
European Procedure (Patents)	11714907.0	07 avr 2011		
Japan	2013-503940	07 avr 2011		

United States Of America 13/639544 07 avr 2011

International Procedure PCT/US2011/031526 07 avr 2011

**Title: A PROCESS FOR THE PREPARATION OF ALPHA' CHLOROKETONES**

Country	Appln. No.	Filing Date	Patent No.	Grant Date
Austria	01961698.6	20 juil 2001	1309535	26 mars 2008
Australia	2001/282944	20 juil 2001	2001282944	01 déc 2005
Belgium	01961698.6	20 juil 2001	1309535	26 mars 2008
Brazil	PI0112820.5	20 juil 2001		
Switzerland	01961698.6	20 juil 2001	1309535	26 mars 2008
China	01814164.1	20 juil 2001	ZL01814164.1	19 juil 2006
Cyprus (Republic)	01961698.6	20 juil 2001	1309535	26 mars 2008
Czech Republic	2003-419	20 juil 2001	301422	14 janv 2010
Germany	01961698.6	20 juil 2001	60133395.0	26 mars 2008
Denmark	01961698.6	20 juil 2001	1309535	26 mars 2008
European Procedure (Patents)	01961698.6	20 juil 2001	1309535	26 mars 2008
Spain	01961698.6	20 juil 2001	1309535	26 mars 2008
Finland	01961698.6	20 juil 2001	1309535	26 mars 2008
France	01961698.6	20 juil 2001	1309535	26 mars 2008
United Kingdom	01961698.6	20 juil 2001	1309535	26 mars 2008
Greece	01961698.6	20 juil 2001	1309535	26 mars 2008
Hong Kong	03104335.3	17 juin 2003	1052001	04 juil 2008
Hungary	P03023344	20 juil 2001		
Ireland	01961698.6	20 juil 2001	1309535	26 mars 2008
Israel	153830	20 juil 2001	153830	01 déc 2012
Italy	01961698.6	20 juil 2001	1309535	26 mars 2008
Japan	2002/519403	20 juil 2001	4889909	22 déc 2011
South Korea	2003-7002215	20 juil 2001	768961	09 oct 2007
Luxembourg	01961698.6	20 juil 2001	1309535	26 mars 2008
Monaco	01961698.6	20 juil 2001	1309535	26 mars 2008
Mexico	PA/A/03/001314	20 juil 2001	232127	11 nov 2005
Netherlands	01961698.6	20 juil 2001	1309535	26 mars 2008
Portugal	01961698.6	20 juil 2001	1309535	26 mars 2008
Sweden	01961698.6	20 juil 2001	1309535	26 mars 2008
Singapore	200300524-6	20 juil 2001	94663	29 oct 2004
Turkey	01961698.6	20 juil 2001	1309535	26 mars 2008
Taiwan	90119584	10 août 2001	NI-233925	11 juin 2005
United States Of America	09/908516	18 juil 2001	6399793	04 juin 2002

International Procedure PCT/US01/23114 20 juil 2001

**Title: STEREOSELECTIVE REDUCTION OF SUBSTITUTED OXO-BUTANES**

Country	Appln. No.	Filing Date	Patent No.	Grant Date
Australia	2001/280698	20 juil 2001	2001280698	09 déc 2005
Brazil	PI0113236.9	20 juil 2001		



China	01814196.X	20 juil 2001	01814196.X	27 avr 2007
Czech Republic	PV2003-758	20 juil 2001	303884	02 mai 2013
Germany	01959109.8	20 juil 2001	1309714	13 mai 2009
European Procedure (Patents)	01959109.8	20 juil 2001	1309714	13 mai 2009
Spain	01959109.8	20 juil 2001	1309714	13 mai 2009
France	01959109.8	20 juil 2001	1309714	13 mai 2009
United Kingdom	01959109.8	20 juil 2001	1309714	13 mai 2009
Hungary	P0300873	20 juil 2001		
Italy	01959109.8	20 juil 2001	1309714	13 mai 2009
Japan	2002-519654	20 juil 2001	3843255	18 août 2006
Mexico	PA/A/03/001312	20 juil 2001	245407	26 avr 2007
Singapore	200300523-8	20 juil 2001	94662	30 nov 2006
Taiwan	90120123	16 août 2001	NI287579	01 oct 2007
United States Of America	10/661893	12 sept 2003	7083973	01 août 2006
International Procedure	PCT/US01/23113	20 juil 2001		

**Title: BMS-232632 HIV PROTEASE INHIBITOR - ATAZANAVIR**

Country	Appln. No.	Filing Date	Patent No.	Grant Date
Argentina	P970101598	21 avr 1997	AR006720B1	29 nov 2005
Austria	97919355.4	14 avr 1997	900210	09 févr 2005
Austria	SZ29/2005	30 juin 2005	SZ29/2005	24 août 2007
Australia	23859/97	14 avr 1997	706183	23 sept 1999
Australia	23859/07	14 avr 1997	706183	23 sept 1999
Belgium	97919355.4	14 avr 1997	900210	09 févr 2005
Belgium	2005C/028	30 juin 2005	2005C/028	06 févr 2007
Brazil	PI9701877-5	22 avr 1997	PI9701877-5	28 sept 2004
Canada	2510945	21 juil 2005	2510945	16 janv 2007
Canada	2568104	01 déc 2006	2568104	04 août 2009
Canada	2250840	14 avr 1997	2250840	04 juil 2006
Switzerland	97919355.4	14 avr 1997	900210	09 févr 2005
Switzerland	C00900210/01	09 févr 2005	C00900210/01	30 juin 2006
Chile	594/2000	14 mars 2000	45096	15 avr 2009
China	01103494.7	16 févr 2001	ZL01103494.7	16 mars 2005
China	200410079187.5	15 sept 2004	200410079187.5	18 avr 2007
China	97194025.8	14 avr 1997	843949	10 avr 2002
Cyprus (Republic)	CY06/00019	28 juil 2006	CY2596	12 mars 2010
Czech Republic	PV1998-3373	14 avr 1997	296135	10 nov 2005
Germany	69732483.4	14 avr 1997	900210	09 févr 2005
Germany	122005000003.5	01 févr 2005	122005000003.5	16 juil 2012
Denmark	97919355.4	14 avr 1997	900210	09 févr 2005
Denmark	CA200500037	11 juil 2005	CR200500037	23 juin 2008
European (Patents)	Procedure 97919355.4	14 avr 1997	900210	09 févr 2005
Spain	97919355.4	14 avr 1997	900210	09 févr 2005
Spain	200500033	17 oct 2008	200500033	17 oct 2008

Finland	97919355.4	14 avr 1997	900210	09 févr 2005
Finland	L20050019	27 juil 2005	260	09 oct 2009
France	97919355.4	14 avr 1997	900210	09 févr 2005
France	05C0030	05 juil 2005	05C0030	27 avr 2007
United Kingdom	97919355.4	14 avr 1997	900210	09 févr 2005
United Kingdom	SPC/GB05/036	21 juil 2005	SPC/GB05/036	06 févr 2006
Greece	97919355.4	14 avr 1997	0900210	09 févr 2005
Greece	2005800019	27 juil 2005	8000186	27 avr 2006
Hong Kong	05107291.6	22 août 2005	1075043	02 nov 2007
Hong Kong	99103921.0	09 sept 1999	HK1018788	05 août 2005
Hungary	P9901612	14 avr 1997	224125	07 avr 2005
Ireland	97919355.4	14 avr 1997	900210	09 févr 2005
Ireland	2005/023	14 avr 1997	900210	12 juin 2006
Israel	126381	14 avr 1997	126381	27 nov 2001
Italy	97919355.4	14 avr 1997	900210	09 févr 2005
Italy	43085	20 juil 2005	892	20 sept 2005
Japan	2004-70023	16 mars 2004		23 févr 2005
Japan	2004-70024	16 mars 2004		23 févr 2005
Japan	537686/1197	14 avr 1997	3174347	30 mars 2001
South Korea	98-0708425	14 avr 1997	486051	27 janv 2005
Luxembourg	97919355.4	14 avr 1997	900210	09 févr 2005
Luxembourg	91189	03 août 2005	91189	03 oct 2005
Mexico	988753	14 avr 1997	207246	19 mars 2002
Malaysia	PI97001496	08 avr 1997	MY-114457-A	31 oct 2002
Netherlands	97919355.4	14 avr 1997	900210	09 févr 2005
Netherlands	300203	28 juil 2005	300203	30 août 2005
Norway	19984900	14 avr 1997	313330	16 sept 2002
New Zealand	509045	20 déc 2000	509045	07 janv 2003
New Zealand	509046	20 déc 2000	509046	09 sept 2002
New Zealand	332118	14 avr 1997	332118	06 juin 2001
Philippines	1-1985-56173	16 avr 1997	1-1997-56173	04 juin 2001
Poland	P329177	14 avr 1997	193822	04 sept 2006
Portugal	97919355.4	14 avr 1997	900210	09 févr 2005
Portugal	205	19 juil 2005	205	04 août 2005
Romania	97919355.4	14 avr 1997	900210	09 févr 2005
Romania	C/067	25 juin 2007	C/067	30 mars 2011
Russian Federation	199800899	14 avr 1997	1794	27 août 2001
Sweden	97919355.4	14 avr 1997	900210	09 févr 2005
Sweden	0590027-9	03 août 2005	0590027-9	10 janv 2006
Singapore	9805564-3	14 avr 1997	60417	21 mars 2000
Slovenia	P9730702	14 avr 1997	900210	09 févr 2005
Slovenia	C200540011	03 août 2005	C200540011	30 avr 2006
Slovakia	PV1452-98	14 avr 1997	PP1452-1998	09 mars 2006
Thailand	9701001436	17 avr 1997		
Taiwan	86104224	02 avr 1997	NI-121586	27 févr 2001

United States Of America	09/399627	20 sept 1999	6166004	26 déc 2000
United States Of America	09/108481	01 juil 1998	6110946	29 août 2000
United States Of America	09/448328	23 nov 1999	6300519	09 oct 2001
United States Of America		14 août 2003	5849911	15 déc 1998
United States Of America	08/831630	09 avr 1997	5849911	15 déc 1998

**Title: BISULFATE SALT OF HIV PROTEASE INHIBITOR**

Country	Appln. No.	Filing Date	Patent No.	Grant Date
Argentina	P990100179	18 janv 1999	AR014417B1	13 avr 2005
Austria	98964878.7	22 déc 1998	1056722	12 juin 2002
Australia	20101/99	22 déc 1998	735875	01 nov 2001
Belgium	98964878.7	22 déc 1998	1056722	12 juin 2002
Bulgaria	104618	22 déc 1998	64774	29 déc 2005
Bulgaria	07/038	13 juin 2007	07/038	16 août 2008
Canada	2317736	22 déc 1998	2317736	02 nov 2004
Switzerland	98964878.7	22 déc 1998	1056722	12 juin 2002
Chile	1999-034	08 janv 1999	41.834	03 juin 2003
China	98812741.5	22 déc 1998	ZL98812741.5	30 juil 2003
Colombia	99002578	19 janv 1999		
Cyprus (Republic)	98964878.7	22 déc 1998	CY 1100263	12 juin 2002
Czech Republic	PV20002564	22 déc 1998	293507	15 mars 2004
Germany	98964878.7	22 déc 1998	69806067.9	12 juin 2002
Denmark	98964878.7	22 déc 1998	1056722	12 juin 2002
Estonia	0425/00PC	22 déc 1998	04434	15 févr 2004
Egypt	56/99	17 janv 1999	23936	14 janv 2008
European (Patents)	Procedure 98964878.7	22 déc 1998	1056722	12 juin 2002
Spain	98964878.7	22 déc 1998	2178300	12 juin 2002
Finland	98964878.7	22 déc 1998	1056722	12 juin 2002
France	98964878.7	22 déc 1998	1056722	12 juin 2002
United Kingdom	98964878.7	22 déc 1998	1056722	12 juin 2002
Greece	98964878.7	22 déc 1998	3040802	12 juin 2002
Hong Kong	01103011.8	26 avr 2001	1033667	24 janv 2003
Hong Kong	01104126.8	15 juin 2001	1033458	07 mai 2004
Hungary	P0101389	22 déc 1998	227196	05 janv 2011
Indonesia	W20001397	22 déc 1998	ID0009860	10 févr 2003
Ireland	98964878.7	22 déc 1998	1056722	12 juin 2002
Israel	137384	22 déc 1998	137384	02 nov 2006
Italy	98964878.7	22 déc 1998	1056722	12 juin 2002
Japan	2000540121	22 déc 1998	4860037	11 nov 2011
Lithuania	2000-067	22 déc 1998	4780	25 avr 2001
Luxembourg	98964878.7	22 déc 1998	1056722	12 juin 2002

Latvia	P0078	22 déc 1998	12522	20 oct 2000
Monaco	98964878.7	22 déc 1998	1056722	12 juin 2002
Mexico	6747	22 déc 1998	215127	08 juil 2003
Malaysia	PI9900020	05 janv 1999	MY-114838	31 janv 2003
Netherlands	98964878.7	22 déc 1998	NL1056722	12 juin 2002
Norway	20003692	22 déc 1998	315605	29 sept 2003
New Zealand	504417	22 déc 1998	504417	10 janv 2002
Peru	0047/99	20 janv 1999	002380	29 avr 2002
Philippines	1-1998-03387	23 déc 1998	1-1998-03387	14 juil 2004
Poland	P342019	22 déc 1998	190744	19 août 2006
Portugal	98964878.7	22 déc 1998	1056722	12 juin 2002
Romania	200000717	22 déc 1998	118869	30 déc 2003
Russian Federation	2000119792	22 déc 1998	2186070	27 juil 2002
Sweden	98964878.7	22 déc 1998	1056722	12 juin 2002
Singapore	200002607-0	22 déc 1998	73159	21 janv 2003
Slovakia	PV1062-2000	22 déc 1998	283975	19 avr 2004
Thailand	048191	14 janv 1999	20875	10 nov 2006
Turkey	00/1876	22 déc 1998	TR200001876B	21 juin 2001
Taiwan	88100623	15 janv 1999	NI-177855	09 sept 2003
Ukraine	2000084931/A	22 déc 1998	59432	15 sept 2003
United States Of America	09/217538	21 déc 1998	6087383	11 juil 2000
Uruguay	25345	12 janv 1999		
Venezuela	1999-000084	20 janv 1999		
International Procedure	PCT/US98/27382	22 déc 1998		



# Schedule D

# Territory

Afghanistan  
 Angola\*  
 Antigua and Barbuda  
 Armenia\*  
 Azerbaijan  
 Bangladesh  
 Belarus\*  
 Belize  
 Benin\*  
 Bhutan  
 Bolivia  
 Botswana\*  
 Burkina Faso\*  
 Burundi\*  
 Cambodia  
 Cameroon\*  
 Cape Verde\*  
 Central African Republic\*  
 Chad\*  
 Comoros\*  
 Congo, Dem. Rep. \*  
 Congo, Rep. \*  
 Costa Rica  
 Côte d'Ivoire\*  
 Cuba  
 Djibouti\*  
 Dominica  
 Dominican Republic\*  
 Ecuador  
 El Salvador  
 Eritrea\*  
 Ethiopia\*  
 Fiji  
 Gabon\*  
 Gambia, The\*  
 Georgia  
 Ghana\*  
 Grenada  
 Guatemala  
 Guinea\*  
 Guinea-Bissau\*  
 Guyana  
 Haiti  
 Honduras  
 India\*  
 Iraq  
 Jamaica  
 Kazakhstan  
 Kenya\*  
 Kiribati  
 Korea, Dem. Rep.  
 Kyrgyz Republic  
 Lao PDR  
 Lesotho\*  
 Liberia\*  
 Libya

Madagascar\*  
 Malawi\*  
 Maldives  
 Mali\*  
 Marshall Island  
 Mauritania\*  
 Mauritius\*  
 Micronesia, Federated States  
 Moldova  
 Mongolia  
 Mozambique\*  
 Myanmar  
 Namibia\*  
 Nauru  
 Nepal  
 Nicaragua\*  
 Niger\*  
 Nigeria\*  
 Pakistan  
 Palau  
 Panama  
 Papua New Guinea  
 Rwanda\*  
 Samoa  
 São Tomé and Príncipe\*  
 Senegal\*  
 Seychelles\*  
 Sierra Leone\*  
 Solomon Islands  
 Somalia\*  
 South Africa\*  
 South Sudan  
 Sri Lanka  
 St. Kitts and Nevis  
 St. Lucia  
 St. Vincent and the Grenadines  
 Sudan\*  
 Suriname  
 Swaziland\*  
 Syrian Arab Republic  
 Tajikistan  
 Tanzania\*  
 Timor-Leste  
 Togo\*  
 Tonga  
 Turkmenistan  
 Tuvalu  
 Uganda\*  
 Uzbekistan  
 Vanuatu  
 West Bank and Gaza  
 Yemen, Rep.  
 Zambia\*  
 Zimbabwe\*

\*Country previously included in one or more BMS agreements in relation to Licensed Patent Rights



**Schedule E      Product Trademark**

Reyataz

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**Schedule F      Technical Transfer Package**

(see attached list)

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## Reyataz TT Overview

BMS-217947 (purchased) + BMS-233110 (purchased)

↓

BMS-233101-01

↓

BMS-214702 (purchased) → BMS-232632-05

### QC Release Methods

Product	Method	Method Number
BMS-232632-05	Identification (IR/ATR)	5315A
BMS-232632-05	Identification (FTIR)	5323A
BMS-232632-05	HPLC (Assay)	5311A
BMS-232632-05	HPLC (Impurities)	248954
BMS-232632-05	HPLC (BMS-214702 Impurity)	249073
BMS-232632-05	KF	003U(G)
BMS-232632-05	Optical Rotation	95009936
BMS-232632-05	Heavy Metals	002B
BMS-232632-05	Residue on Ignition	006C
BMS-232632-05	Titration/Counter ion	248960
BMS-232632-05	GC (residual solvent)	248961
BMS-232632-05	Particle Size	5312A (95009048)
BMS-233101-01	Identification (IR/KBr)	0100
BMS-233101-01	HPLC (Assay and Impurities)	249036
BMS-217947-01	Identification (IR/KBr)	0100
BMS-217947-01	Identification (IR/ATR)	5315A
BMS-217947-01	Identification (FTIR)	5323A
BMS-217947-01	HPLC (Purity/Impurity)	248967
BMS-217947-01	HPLC (Enantiomer check)	248966
BMS-217947-01	GC (residual solvent)	5316A
BMS-217947-01	GC (collidine)	250477
BMS-233110-01	Identification (IR/KBr)	0100
BMS-233110-01	Identification (Raman)	5459A
BMS-233110-01	HPLC (Purity/Impurity)	248969
BMS-233110-01	HPLC (BMS-566370 impurity)	249059
BMS-233110-01	Heavy Metals (ICP)	248981
BMS-233110-01	GC (residual solvent)	5316A

Product	Method	Method Number
BMS-214702-01	Identification (IR/KBr)	0100
BMS-214702-01	Identification (Raman)	5459A
BMS-214702-01	HPLC (Assay/Impurity)	248972



BMS-214702-01	HPLC (Enantiomer check)	248965
BMS-214702-01	GC (residual solvent)	5316A
Cleaning Method	HPLC (cleaning after 632)	QC-CM-ATA-001
Cleaning Method	HPLC(cleaning after 101, 947 and 110)	QC-CM-ATA-002
Cleaning Method	HPLC (cleaning after 702)	QC-CM-ATA-003

#### IPC Methods

Product	Method	Method Number
BMS-232632-05	HPLC	ATA01001
BMS-232632-05	GC (DCM check)	ATA01002
BMS-232632-05	General method (pH,KF etc)	ATA01003
BMS-232632-05	HPLC (purity)	ATA01004
BMS-232632-05	GC (NMPO check)	ATA01005
BMS-232632-05	Raman (DCM check)	ATA01006
BMS-232632-05	IR-LOD	ATA01007
BMS-233101-01	HPLC	ATA02001
BMS-233101-01	LOD	ATA02002

#### Process Documents

Product	Document	Document Number
BMS-232632-05	Process Flow Diagram	MFG-PFD-P8-001
BMS-233101-01	Process Flow Diagram	MFG-PFD-P5-001

#### Regulatory Documents

Product	Document	Document Number
BMS-232632-05	Process description	QA-REG-ATA-002
BMS-233101-01	Process description	QA-REG-ATA-002

#### Safety Documents

Product	Document	Document Number
BMS-232632-05	MSDS	MSDS – BMS-214702-01
BMS-232632-05	MSDS	MSDS – BMS-233101-01
BMS-232632-05	MSDS	MSDS – BMS-232632-01
BMS-232632-05	MSDS	MSDS – BMS-232632-05
BMS-233101-01	MSDS	MSDS – BMS-217947-01
BMS-233101-01	MSDS	MSDS – BMS-233110-01
BMS-233101-01	MSDS	MSDS – BMS-233101-01

## Reyataz Capsules Overview

### QC Release Methods

Method	Method Number
<b>Description</b>	-
<b>IR/ATR</b>	248993(S)
<b>HPLC ID</b>	5307A(G)
<b>Potency</b>	5307A(G)
<b>Imps/ Degs</b>	5308A(G)
<b>Uniformity of Dosage Units</b> (Weight Variation)	249917(S) 356X(G)
<b>Dissolution</b>	248959(S) 311(G)
<b>Microbial Limits</b>	
Total Aerobic Microbial Count	248971(S)
Total Yeasts	248971(S)
E. Coli	248971(S)

### Specifications

Document	Document Number
Reyataz Finished Product	3.2.P.5.1
Excipient specifications	3.2.P.4.2
Capsule specification	3.2.P.4.1

### Process Documents

Document	Document Number
Batch Formula	3.2.P.3.2.T01
Process Flow Diagram/Process Description	3.2.P.3.3

